

industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term *polychlorinated biphenyls* (PCB's) is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 0.2 part per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).

(2) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food-producing animals.

(3) 10 parts per million in paper food-packaging material intended for or used with finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerances established in this section is available from the Dockets Management Branch, Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

[42 FR 52821, Sept. 30, 1977, as amended at 46 FR 8460, Jan. 27, 1981; 59 FR 14365, Mar. 28, 1994]

Subpart C—Regulatory Limits for Added Poisonous or Deleterious Substances [Reserved]

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PART 510—NEW ANIMAL DRUGS

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Subpart G—Sponsors of Approved Applications

510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

SOURCE: 40 FR 13807, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 510.3 Definitions and interpretations.

As used in this part:

(a) The term *act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–902, 52 Stat. 1040 *et seq.*, as amended; 21 U.S.C. 321–392).

(b) *Department* means the Department of Health and Human Services.

(c) *Secretary* means the Secretary of Health and Human Services.

(d) *Commissioner* means the Commissioner of Food and Drugs.

(e) *Person* means individuals, partnerships, corporations, and associations.

(f) The definitions and interpretations of terms contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

(g) The term *new animal drug* means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed:

(1) The composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a *new animal drug* if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) The composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which

has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(h) The term *animal feed* means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(i) The newness of an animal drug, including a new animal drug intended for use in or on animal feed, may arise by reason of: (1) The newness for its intended drug use of any substance of which the drug is comprised, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component; (2) the newness for its intended drug use of a combination of two or more substances, none of which is itself a new animal drug; (3) the newness for its intended drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new animal drug; (4) the newness for its intended drug use in a different species of animal; (5) the newness of its intended drug use in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the animal body, even though such drug is not a new animal drug when used in another disease or to affect another structure or function of the body; or (6) the newness of a dosage, or method or duration of administration or application, or any other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug or animal feed containing such drug when used in another dosage, or another method or duration of administration or application, or different condition, is not a new animal drug.

(j) *Animals used only for laboratory research* and *laboratory research animals* mean individual animals or groups of animals intended for use and used solely for laboratory research purposes, regardless of species, and does not include animals intended to be used for any food purposes or animals intended to be kept as livestock.

(k) The term *sponsor* means the person responsible for an investigation of a new animal drug, including responsibility for compliance with applicable provisions of the act and regulations. The *sponsor* may be an individual, partnership, corporation, or Government agency or may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of new animal drugs.

[40 FR 13807, Mar. 27, 1975, as amended at 50 FR 7517, Feb. 22, 1985; 54 FR 22741, May 26, 1989; 64 FR 69190, Dec. 10, 1999]

§ 510.4 Biologics; products subject to license control.

An animal drug produced and distributed in full conformance with the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 *et seq.*) and any regulations issued thereunder shall not be deemed to be subject to section 512 of the Federal Food, Drug, and Cosmetic Act.

§ 510.7 Consignees of new animal drugs for use in the manufacture of animal feed.

(a) A new animal drug intended for use in the manufacture of animal feed shall be deemed to be unsafe unless at the time of its removal from the establishment of a manufacturer, packer, or distributor of such drug, such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or a notice from the Secretary, to the effect that with respect to the use of such drug in animal feed the consignee:

(1) Holds a license issued under § 515.20 of this chapter; or

(2) Will, if the consignee is not the user of the drug, ship such drug only to a holder of an approved application under § 515.10 of this chapter.

(b) The requirements of paragraph (a) of this section do not apply:

(1) Where such drugs are intended for export and/or

(2) When the use of such drug in the manufacture of a finished feed has been exempted from the requirements of section 512(m) of the act under the conditions specified by regulations published in part 558 of this chapter.

[40 FR 13807, Mar. 27, 1975, as amended at 64 FR 63203, Nov. 19, 1999]

§ 510.95 [Reserved]

Subpart B—Specific Administrative Rulings and Decisions

§ 510.105 Labeling of drugs for use in milk-producing animals.

(a) Part 526 of this chapter provides for new animal drugs intended for intramammary use in animals and includes conditions of use intended to prevent the contamination of milk from the use of such drugs.

(b) Preparations containing antibiotics and other potent drugs labeled with directions for use in milk-producing animals will be misbranded under section 502(f)(2) of the act unless their labeling bears appropriate warnings and directions for use to avoid adulteration of milk under section 402(a)(2)(c)(ii) of the act.

(c) It is the position of the Food and Drug Administration that the labeling for such preparations should bear a clear warning that either:

(1) The article should not be administered to animals producing milk, since to do so would result in contamination of the milk; or

(2) The label should bear the following statement: “Warning: Milk that has been taken from animals during treatment and for ___ hours after the latest treatment must not be used for food”, the blank being filled in with the figure that the manufacturer has determined by appropriate investigation is needed to insure that the milk will not carry violative residues resulting from use of the preparation. If the use of the preparation as recommended does not result in contamination of the milk, neither of the above warning statements is required.

[40 FR 13807, Mar. 27, 1975, as amended at 63 FR 32980, June 17, 1998; 64 FR 51241, Sept. 22, 1999]

§ 510.106 Labeling of antibiotic and antibiotic-containing drugs intended for use in milk-producing animals.

Whenever the labeling of an antibiotic drug included in the regulations in this chapter suggests or recommends its use in milk-producing animals, the label of such drugs shall bear either the statement “Warning: Not for use in animals producing milk, since this use

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will result in contamination of the milk” or the statement “Warning: Milk that has been taken from animals during treatment and for ___ hours after the latest treatment must not be used for food”, the blank being filled in with the figure that the Commissioner has authorized the manufacturer of the drug to use. The Commissioner shall determine what such figures shall be from information submitted by the manufacturer and which the Commissioner considers is adequate to prove that period of time after the latest treatment that the milk from treated animals will contain no violative residues from use of the preparation. If the Commissioner determines from the information submitted that the use of the antibiotic drug as recommended does not result in its appearance in the milk, the Commissioner may exempt the drug from bearing either of the above warning statements.

[63 FR 32980, June 17, 1998]

§510.110 Antibiotics used in food-producing animals.

(a) The Food and Drug Administration in the interest of fulfilling its responsibilities with regard to protection of the public health has requested an evaluation of the public health aspects of the use of antibiotics in veterinary medical and nonmedical uses. There is particular concern with regard to the potential hazards associated with the extensive use of antibiotics administered to food-producing animals. Accordingly, an ad hoc committee on the Veterinary Medical and Nonmedical Uses of Antibiotics was established by the Food and Drug Administration to study and advise the Commissioner of Food and Drugs on the uses of antibiotics in veterinary medicine and for various nonmedical purposes as such uses may affect the enforcement of the Federal Food, Drug, and Cosmetic Act with respect to their safety and effectiveness.

(b) Based upon an evaluation of the conclusions of said Committee and other relevant material, §510.112 was published in the FEDERAL REGISTER of August 23, 1966 (31 FR 11141), asking sponsors of drugs containing any antibiotic intended for use in food-producing animals to submit data to es-

tablish whether such antibiotic and its metabolites are present as residues in edible tissues, milk, and eggs from treated animals. The data on the residues of antibiotics in milk from intramammary infusion preparations were requested within 60 days and the data on all other products were requested within 180 days following the date of publication of §510.112 in the FEDERAL REGISTER.

(c) An evaluation of the data now available shows that use of many antibiotic preparations cause residues in edible products of treated animals for varying and, in some cases, for long periods of time following the last administration. Because of the accumulation of new information with regard to the development of resistance of bacteria to antibiotics, the ability of bacteria to transfer this resistance, and the development of sensitivity to antibiotics in humans, unauthorized and unsafe residues of antibiotics cannot be permitted in food obtained from treated animals.

(d) Based on evaluation of information available, including the conclusions of the aforementioned ad hoc Committee, the Commissioner concludes that antibiotic preparations intended for use in food-producing animals, other than topical and ophthalmic preparations, are not generally recognized among qualified experts as having been shown to be safe for their intended use(s) within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act.

(e) Therefore, all exemptions from the provisions of section 409 of the act for use of antibiotics in food-producing animals based on sanctions or approvals granted prior to enactment of the Food Additives Amendment of 1958 (Pub. L. 85-929; 72 Stat. 1784) will be revoked and the uses which are concluded to be safe will be covered by food additive regulations. On those products for which there are inadequate residue data, actions will be initiated to withdraw approval of new-drug applications under the provisions of section 505 of the act. Antibiotic preparations, other than those for topical and ophthalmic application in food-producing animals, which are not covered by food additive regulations will be subject to regulatory action

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within 180 days after publication of the forthcoming revocation order.

(f) Because of the variation in the period of time that antibiotic residues may remain in edible products from treated animals, all injectable, intramammary infusion, intrauterine, and oral preparations, including medicated premixes intended for use in food-producing animals, are deemed to be new drugs as well as food additives.

[40 FR 13807, Mar. 27, 1975, as amended at 54 FR 18280, Apr. 28, 1989; 64 FR 403, Jan. 5, 1999]

§ 510.112 Antibiotics used in veterinary medicine and for nonmedical purposes; required data.

(a) An ad hoc committee, Committee on the Veterinary Medical and Non-medical Uses of Antibiotics, was formed by the Food and Drug Administration to study, and advise the Commissioner on, the use of antibiotics in veterinary medicine and for various nonmedical purposes as such uses may affect the enforcement of the Federal Food, Drug, and Cosmetic Act with respect to the safety and effectiveness of such substances. A copy of the report may be obtained from the Food and Drug Administration, Office of Public Affairs, Room 15-05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

(b) On the basis of the report of the Committee and other information, sponsors of drugs containing any antibiotic intended for use in food-producing animals shall submit data for determining whether or not such antibiotics and their metabolites are present as residues in edible tissues, milk, and eggs from treated animals; however, in the case of a drug for which such data have already been submitted and for which a regulation has been promulgated under section 409 of the act, only such data as has been accumulated since the issuance of the regulation need be submitted.

(c) The required data shall be submitted within 180 days of the date of publication of this section in the FEDERAL REGISTER; except that in the case of data on intramammary infusion preparations the data shall be submitted within 60 days of such publication. Data demonstrating the absence in milk of residues of intramammary

infusion preparations when used as directed in their labeling are needed within the 60-day period because of the importance of milk in the human diet.

(d) Regulatory proceedings including revocation of prior sanctions, or actions to suspend or amend new drug or antibiotic approvals granted prior to passage of the Food Additives Amendment of 1958 (72 Stat. 1784), may be initiated with regard to the continued marketing of any antibiotic preparation on which the required information is not submitted within the period of time prescribed by paragraph (c) of this section.

(e) Questions relating to the acceptability of proposed research protocols and assay methods for determining the amount of antibiotic residues in food should be directed to the Director, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

[40 FR 13807, Mar. 27, 1975, as amended at 46 FR 8460, Jan. 27, 1981; 54 FR 18280, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992]

Subpart C [Reserved]

Subpart D—Records and Reports

§ 510.300 Records and reports concerning experience with new animal drugs for which an approved application is in effect.

(a) On receiving notification that an application submitted pursuant to § 514.1 of this chapter for a new animal drug is approved, the applicant shall establish and maintain such records and make such reports as are specified in this section to facilitate a determination as to whether there may be grounds for suspending or withdrawing approval of the application or whether any applicable regulation should be amended or repealed. The applicant shall maintain adequately organized and indexed files containing full reports of information pertinent to the safety or effectiveness of the new animal drug that have not previously been submitted as part of his application for the drug and which are received or otherwise obtained by him from any source, as follows:

(1) Unpublished reports of clinical or other animal experience, studies, investigations, and tests conducted by the applicant or reported to him by any person involving the new animal drug that is the subject of the application or any related drugs. An adequate summary and bibliography of reports in the scientific literature would ordinarily suffice. (The application must identify at the time of each report submission, each drug he considers related to the subject drug.)

(2) Experience, investigations, studies, or tests involving the chemical or physical properties or any other properties of the new animal drug, such as its behavior or properties in relation to microorganisms, including both the effects of the drug on microorganisms and the effect of microorganisms on the drug.

(3) For information required by this section, adequate identification of its source, when known, including the name and post office address of the person who furnishes such information.

(4) Copies of all mailing pieces and other labeling, and, if it is a prescription new animal drug or a veterinary feed directive drug, all advertising other than that contained in the application used in promoting the drug, and copies of the currently used package labeling that gives full information for use of the drug whether or not such labeling is contained in the application.

(5) Information concerning the quantity of the new animal drug distributed in a manner and form that facilitates estimates of the incidence of any adverse effects reported to be associated with the use of the drug. This does not require disclosure of financial, pricing, or sales data.

(6) Information concerning any previously unreported changes from the conditions described in an application conforming to the conditions of § 514.8(a)(5) of this chapter.

(b) The applicant shall submit to the Food and Drug Administration copies of the records and reports described in paragraph (a) of this section, except routine assay and control records, appropriately identified with the new animal drug application(s) to which they relate, as follows:

(1) Immediately upon receipt by the applicant, complete records or reports covering information of the following kinds:

(i) Information concerning a mixup in the new animal drug or its labeling with another article.

(ii) Information concerning any bacteriological or significant physical or other change or deterioration in the new animal drug, or any failure of one or more distributed batches of the drug to meet the specifications established for it in the new animal drug application.

(2) As soon as possible, and in any event within 15 working days of its receipt by the applicant, complete records of reports concerning any information of the following kinds:

(i) Information concerning any unexpected side effects, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical use, studies, investigations, or tests, whether or not determined to be attributable to the new animal drug, except that this requirement shall not apply to the submission of information described in a written communication to the applicant from the Food and Drug Administration as types of information that may be submitted at other designated intervals. *Unexpected* as used in this subdivision refers to conditions or developments not previously submitted as part of the new animal drug application, or conditions and developments occurring at a rate higher than that shown by information previously submitted as part of the application.

(ii) Information concerning any unusual failure of the new animal drug to exhibit its expected pharmacological activities.

(3) When mailing pieces, any other labeling, and advertising are devised for promotion of the new animal drug, specimens shall be submitted at the time of initial dissemination of such labeling and at the time of initial publication of any advertisement for a prescription drug. Mailing pieces and labeling designed to contain samples of a drug shall be complete except for the omission of the drug.

(4) All the kinds of information described in paragraph (a) of this section,

other than that submitted under the provisions of paragraphs (b) (1), (2), and (3) of this section, shall be submitted as follows unless otherwise ordered in a written communication from the Commissioner:

(i) At intervals within 6 months beginning with the date of approval of the new animal drug application during the first year following such date, and at yearly intervals thereafter.

(ii) Whenever an applicant is required to submit reports under the provisions of paragraph (b)(4)(i) of this section with respect to more than one approved application for preparations containing the same new animal drug so that the same item(s) of information is (are) required to be reported for more than one application, he may elect to submit as a part of the report for one such application all the information common to such applications in lieu of reporting separately and repetitively on each. The applicant shall state when this is done and identify all the new animal drug applications for which the reports are submitted.

(iii) The submitted copies of records and reports shall include all the required information that was received or otherwise obtained by the applicant during the designated intervals.

(5) On written order of the Commissioner, within the time stated in such order or agreed to by the applicant and the Commissioner, any designated records or reports containing the kinds of information described in this section shall be submitted.

(c) The applicant shall, upon request of any properly authorized officer or employee of the Department at reasonable times, permit such officers to have access to and copy and verify any records and reports established and maintained under the provisions of this section.

(d) If the Food and Drug Administration finds that the applicant has failed to establish a system for maintaining required records or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with the provisions of this section, or that the applicant has refused to permit access to or copying of, or verification of such records or reports, the Commissioner shall give the

applicant notice and opportunity for a hearing on the question of whether to withdraw the approval of the application, as provided in §514.200 of this chapter.

(e) Upon written request of the applicant stating reasonable grounds therefor, the Commissioner will make available any information in possession of the Food and Drug Administration of the kinds the applicant is required to maintain under the provisions of this section, except information readily available to the applicant from other sources or information which the Commissioner concludes is confidential.

(f) The *applicant* required to establish and maintain records and make reports required by this section includes any person whose name appears on the labeling of the drug as its manufacturer, packer, or distributor under an approval or who is engaged in the manufacturing, processing, packing, or labeling of the drug under an approval of the new animal drug application or any supplement to it; however, to avoid unnecessary duplication in the submission of reports, any such applicant's obligation to submit a report may be met by its submission on his behalf, designated as such, by another person responsible for reporting.

[40 FR 13807, Mar. 27, 1975, as amended at 65 FR 76928, Dec. 8, 2000]

§510.301 Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved medicated feed mill license application is in effect.

Records and reports of clinical and other experience with the new animal drug will be maintained and reported, appropriately identified with the new animal drug application(s) to which they relate, to the Center for Veterinary Medicine in duplicate in accordance with the following:

(a) Immediately upon receipt by the applicant, complete records or reports covering information of the following kinds:

(1) Information concerning any mixup in the new animal drug or its labeling with another article.

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(2) Information concerning any bacteriological, or any significant chemical, physical, or other change or deterioration in the drug, or any failure of one or more distributed batches of the drug to meet the specifications established for it in the new animal drug application.

(b) As soon as possible, and in any event within 15 working days of its receipt by the applicant, complete records or reports concerning any information of the following kinds:

(1) Information concerning any unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical uses, studies, investigations, or tests, whether or not determined to be attributable to the new animal drug, except that this requirement shall not apply to the submission of information described in a written communication to the applicant from the Food and Drug Administration as types of information that may be submitted at other designated intervals. *Unexpected* as used in this paragraph refers to conditions or developments not previously submitted as part of the new animal drug application or not encountered during clinical trials of the drug, or conditions or developments occurring at a rate higher than shown by information previously submitted as part of the new animal drug application or at a rate higher than encountered during such clinical trials.

(2) Information concerning any unusual failure of the new animal drug to exhibit its expected pharmacological activity.

[40 FR 13807, Mar. 27, 1975, as amended at 54 FR 18280, Apr. 28, 1989]

§ 510.302 Reporting forms.

(a) The information described in § 510.300, except that described in paragraphs (b) (1) and (2) of that section, shall be submitted appropriately identified with the new animal drug application(s) to which they relate in duplicate on Form FD-2301 “Transmittal of Periodic Reports and Promotional Material for New Animal Drugs.”

(b) All adverse experiences with new animal drugs as described in § 510.300(b)(2) or § 510.301(b) whether or not related to a required periodic re-

port submitted on a Form FD-2301, shall be reported on Form FD-1932 “Adverse Drug Reaction” (except as provided in paragraph (c) of this section). Reports of adverse drug experiences may be submitted initially in the form of a written communication, but any such communication shall be followed promptly (but not necessarily within the prescribed 15 working days) by a completed Form FD-1932. A separate “Adverse Drug Reaction” form should be submitted for each patient where feasible.

(c) In lieu of Form FD-1932 the holder of an approved new animal drug application may submit:

(1) A computerized report if the information contained therein and the sequence in which it is presented are equivalent to that required by Form FD-1932 and the report is submitted in duplicate. Such reports will require initial approval by the Food and Drug Administration prior to use; and

(2) Copies of reports of reactions appearing in the published scientific literature may be submitted.

(d) Forms FD-1932 and FD-2301, with instructions for their use, may be obtained from the Food and Drug Administration, Department of Health and Human Services, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

[40 FR 13807, Mar. 27, 1975, as amended at 41 FR 35844, Aug. 25, 1976; 54 FR 18280, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992]

§ 510.305 Maintenance of copies of approved medicated feed mill licenses to manufacture animal feed bearing or containing new animal drugs.

Each applicant shall maintain in a single accessible location:

(a) A copy of the approved medicated feed mill license (Form FDA 3448) on the premises of the manufacturing establishment; and

(b) Approved labeling for each Type B and/or Type C feed being manufactured on the premises of the manufacturing establishment or the facility where the feed labels are generated.

[64 FR 63203, Nov. 19, 1999]

Subpart E—Requirements for Specific New Animal Drugs**§ 510.410 Corticosteroids for oral, injectable, and ophthalmic use in animals; warnings and labeling requirements.**

(a) The Food and Drug Administration has received reports of side effects associated with the oral, injectable, and ophthalmic use of corticosteroid animal drugs. The use of these drugs administered orally or by injection has resulted in premature parturition when administered during the last trimester of pregnancy. Premature parturition may be followed by dystocia, fetal death, retained placenta, and metritis. Additionally, corticosteroids used in dogs, rabbits, and rodents during pregnancy have produced cleft palate in offspring. Use in dogs has resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca. Drugs subject to this section are required to carry the veterinary prescription legend and are subject to the labeling requirements of § 201.105 of this chapter.

(b) In view of these potentially serious side effects, the Food and Drug Administration has concluded that the labeling on or within packaged corticosteroid-containing preparations intended for animal use shall bear conspicuously the following warning statement:

Warning: Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca.

[49 FR 48535, Dec. 13, 1984]

§ 510.440 Injectable iron preparations.

There has been an increasing interest in the use of injectable iron compounds for the prevention or treatment of iron-deficiency anemia in animals. Although some such preparations have

been shown to be safe, such articles are regarded as new animal drugs within the meaning of the Federal Food, Drug, and Cosmetic Act. Accordingly, an approved new animal drug application is required prior to the marketing of such preparations within the jurisdiction of the act. In addition to the need for demonstrating the safety of such articles, the labeling of such preparations should not only recommend appropriate dosages of iron but also declare the amount (in milligrams) of available iron (Fe) per milliliter of the subject product.

§ 510.455 New animal drug requirements regarding free-choice administration in feeds.

(a) For the purpose of this section, free-choice administration of animal drugs in feeds involves feeds that are placed in feeding or grazing areas and are not intended to be consumed fully at a single feeding or to constitute the entire diet of the animal. Such methods of administering drugs include, but are not limited to, medicated blocks (agglomerated feed compressed or rendered into a solid mass and cohesive enough to hold its form), mineral mixes, and liquid feed tank supplements ("lick tank" supplements) containing one or more animal drugs. The manufacture of medicated free-choice feeds is subject to the current good manufacturing practice regulations for medicated feeds.

(b) The Food and Drug Administration has concluded that there are questions about the safety and effectiveness of drugs when administered in free-choice feeds. Therefore, such methods of administration cause the drugs so administered to be new animal drugs, for which approved new animal drug applications (NADA's) are required. (See § 510.3(i)). In addition, the exemption from the requirement of an approved medicated feed application provided in § 558.4 of this chapter does not apply to any free-choice medicated feed.

(c) An NADA or supplemental NADA for products for free-choice feeding submitted for approval under section 512(b) of the act shall provide for:

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(1) The manufacture of a finished product for the free-choice administration of a new animal drug. Such an approval will not provide a basis upon which an application can be approved under section 512(m) of the act; or

(2) The manufacture of a Type A medicated article for use in the subsequent manufacture of a free-choice medicated feed. The approved NADA will provide a basis upon which an application can be approved under section 512(m) of the act. Data for a specific free-choice product may, if desired, be generated and submitted to the Food and Drug Administration by the manufacturer of the free-choice feed in the form of a master file which can be referenced in the NADA or supplemental NADA submitted by the new animal drug sponsor.

(d) Approval of the NADA or supplemental NADA submitted under paragraph (c) of this section will be reflected in a regulation in part 558 of this chapter published under section 512(i) of the act. The regulation will either state the formulation of the approved free-choice product or specify the specific free-choice administration products in which the drug is approved for use. If the approval is for a Type A medicated article, the regulation in part 558 of this chapter will indicate that each use of the Type A medicated article in a free-choice product must be the subject of an approved supplemental NADA.

(e) An application submitted under section 512(m) of the act to provide for manufacture of a specific free-choice feed from an approved Type A medicated article will be approved if, in addition to the information required by the medicated feed application, it includes a reference to the exact formula of the product to be manufactured as follows:

(1) The formula is the same as the one published in the new animal drug regulations; or

(2) The data in a master file have been referenced in an NADA or supplemental NADA; and

(3) Use of the Type A medicated article in the specific formulation has been approved on the basis that:

(i) The formula is the same as the one for which acceptable data have

been submitted in a master file by the medicated feed applicant; or

(ii) The medicated feed applicant has written authority to reference a master file that has acceptable data for the formula in question.

(Approved by the Office of Management and Budget under control number 0910-0205)

[51 FR 19827, June 3, 1986]

Subpart F—Animal Use Exemptions From Certification and Labeling Requirements

§510.515 Animal feeds bearing or containing new animal drugs subject to the provisions of section 512(n) of the act.

Animal feeds that bear or contain penicillin, chlortetracycline, feed grade zinc bacitracin, and bacitracin methylene disalicylate, with or without added suitable nutritive ingredients are exempt from the certification requirements of section 512 of the act provided they are the subject of and in compliance with regulations for their use in this subchapter E, part 558 of this chapter, or any one of the paragraphs of this section:

(a) Where indicated in paragraph (b) of this section it is manufactured with or without one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(1) Arsanilic acid: Not less than 0.005 percent and not more than 0.01 percent.

(2) Sodium arsanilate: Not less than 0.005 percent and not more than 0.01 percent.

(3) 3-Nitro-4-hydroxyphenylarsonic acid: Not less than 0.0025 percent and not more than 0.0075 percent except in chicken or turkey feed which shall contain not less than 0.0025 percent and not more than 0.005 percent.

(b) It is intended for use in any one of the following conditions set forth in this paragraph:

(1) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection), infectious sinusitis, and blue comb (nonspecific infectious enteritis) in poultry and/or bacterial swine enteritis; its labeling bears adequate directions and warnings for such use; and it contains, per ton of

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feed, the equivalent of 100 grams of penicillin. When intended for uses specified in this paragraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section.

(2) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection) and infectious

sinusitis in poultry; its labeling bears adequate directions and warnings for such use; and it contains not less than 0.1 percent para-aminobenzoic acid or the sodium or potassium salt or para-aminobenzoic acid.

(3)–(29) [Reserved]

(c) It is intended for use as follows:

Product	Species	Use levels	Indications for use
1. Nicarbazin	Chickens	0.01 to 0.02 percent	For use in the prevention of outbreaks of coccidiosis in poultry flocks; growth promotion and feed efficiency. Do.
.....dodo	2.4 to 50 g/ton	
2. Nicarbazindo	0.01 to 0.02 percent	Do.
Bacitracin methylene disalicylate.do	4 to 50 g/ton.	
3. Nicarbazindo	0.01 to 0.02 percent	For use as an aid in the prevention of coccidiosis in poultry flocks; growth promotion and feed efficiency; improving pigmentation.
Bacitracin methylene disalicylate.do	4 to 50 g/ton.	
3-Nitro-4-hydroxyphenylarsonic acid.do	0.0025 to 0.005 percent.	Do.
4. Nicarbazindo	0.01 to 0.02 percent	
Procaine penicillindo	2.4 to 50 g/ton.	Enhancement of growth and feed efficiency.
3-Nitro-4-hydroxyphenylarsonic acid.do	0.0025 to 0.005 percent.	
5. Chlortetracycline	Swine	10 to 50 g/ton	Do.
Arsanilic aciddo	0.005 to 0.01 percent.	

[41 FR 8299, Feb. 25, 1976, as amended at 41 FR 11011, Mar. 15, 1976; 42 FR 18614, Apr. 8, 1977; 47 FR 42102, Sept. 24, 1982; 47 FR 51563, Nov. 16, 1982; 56 FR 41912, Aug. 23, 1991; 58 FR 30119, May 26, 1993; 61 FR 35950, July 9, 1996]

(c) The names, addresses, and drug labeler codes of sponsors of approved new animal drug applications are as follows:

(1) ALPHABETICAL LISTING OF SPONSORS

Subpart G—Sponsors of Approved Applications

§510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

(a) Section 512(i) of the act requires publication of names and addresses of sponsors of approved applications for new animal drugs.

(b) In this section each name and address is identified by a numerical drug labeler code. The labeler codes identify the sponsors of the new animal drug applications associated with the regulations published pursuant to section 512(i) of the act. The codes appear in the appropriate regulations and serve as a reference to the names and addresses listed in this section. The drug labeler code is established pursuant to section 510 of the act.

Firm name and address	Drug labeler code
Abbott Laboratories, North Chicago, IL 60064 ...	000074
ADM Animal Health & Nutrition Division, 1000 North 30th St., Box 1C, Quincy, IL 62305–3115	017519
Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464	024174
Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503	057561
Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112	017762
Akey, Inc., P.O. Box 607, Lewisburg, OH 45338	017790
Akzo Nobel Surface Chemistry AB, Box 851, S–44485 Stenungsund, Sweden	063765
Alaco, Inc., 1500 North Wilmot Rd., suite 290–C, Tucson, AZ 85712	064146
Albion Laboratories, Inc., 101 North Main, Clearfield, UT 84015	011485
Alpharma Inc., One Executive Drive, P.O. Box 1399, Fort Lee, NJ 07024	046573
Alstoe, Ltd., Animal Health, Granary Chambers, 37–39 Burton St., Melton Mowbray, Leicestershire LE13 1AF, England	062408
Altana Inc., 60 Baylis Rd., Melville, NY 11747 ...	025463

(1) ALPHABETICAL LISTING OF SPONSORS—
Continued

Firm name and address	Drug label- er code
American Cyanamid, Division of American Home Products, P.O. Box 1339, Fort Dodge, IA 50501	010042
American Pharmaceuticals Partners, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160 ...	063323
Anika Therapeutics Inc., 236 West Cummings Park, Woburn, MA 01801	060865
Anthony Products Co., 5600 Peck Rd., Arcadia, CA 91006	000864
Argent Laboratories, 8702 152d Ave. NE., Redmond, WA 98052	051212
Ausa International, Inc., Rt. 8, P.O. Box 324–12, Tyler, TX 75703	059521
Aventis Animal Nutrition, Inc., 3480 Preston Ridge Rd., suite 650, Alpharetta, GA 30005–8891	011526
Balfour Guthrie & Co., Ltd., 315 North H St., Fresno, CA 93701	043728
Baxter Pharmaceutical Products, Inc., 110 Allen Rd., Liberty Corner, NJ 07938	010019
Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee, Mission, KS 66201 ..	000859
Bimeda, Inc., 288 County Rd. 28, LeSueur, MN 56058–9322	061133
Biocraft Laboratories, Inc., 92 Route 46, Elmwood Park, NJ 07407	000332
Bioproducts, Inc., 320 Springside Dr., Suite 300, Fairlawn, OH 44333–2435	051359
Biopure Corp., 11 Hurley St., Cambridge, MA 02141	063075
BioScience Division of Milk Specialties Co., Illinois and Water Sts., P.O. Box 278, Dundee, IL 60118	032761
Blue Ridge Pharmaceuticals, Inc., 4249–105 Piedmont Pkwy., Greensboro, NC 27410	065274
Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002	000010
Carnation Co., 5045 Wilshire Blvd., Los Angeles, CA 90036	047019
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland	061651
Chemdex, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215	017287
Combe, Inc., 1101 Westchester Ave., White Plains, NY 10604	011509
ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105	021091
Contemporary Products, Inc., 3788 Elm Springs Rd., Springdale, AR 72764–6067	055462
Cooperative Research Farms, Box 69, Charlotteville, NY 12036	051267
Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland	061623
Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501	046987
Custom Feed Services Corp., 2100 N. 13th St., Norfolk, NE 68701	017473
Cyanamid Agricultural de Puerto Rico, Inc., P.O. Box 243, Manati, PR 00701	043781
Delmarva Laboratories, Inc., 2200 Wadebridge Rd., P.O. Box 525, Midlothian, VA 23113	059079
Diamond Shamrock Corp., Nutrition & Animal Health Div., 1100 Superior Ave., Cleveland, OH 44114	025001
DuPont Merck Pharmaceutical Co., DuPont Merck Plaza, MR2117, Wilmington, DE 19805 ..	000056
Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285	000986

(1) ALPHABETICAL LISTING OF SPONSORS—
Continued

Firm name and address	Drug label- er code
Endo Pharmaceuticals, Inc., 223 Wilmington West Chester Pike, Chadds Ford, PA 19317 ..	060951
Eon Labs Manufacturing, Inc. 227-15 North Conduit Ave., Laurelton, NY 11413	000185
Equi Aid Products, Inc., 1517 West Knudsen Dr., Phoenix, AZ 85027	062240
Evsco Pharmaceuticals, An Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310	017030
Farmers Feed & Supply Co., Ninth St. at Northwestern Tracks, Tipton, IA 52772	043744
Farmland Industries, Inc., Kansas City, MO 64116	021676
Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013–3928	017135
Feed Service Co., Inc., 303 Lundin Blvd., P.O. Box 698, Mankato, MN 56001	030841
John J. Ferrante, 11 Fairway Lane, Trumbull, CT 06611	058034
First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123	058829
Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234	015565
Fort Dodge Animal Health, A Division of American Cyanamid Co., P.O. Box 1339, Fort Dodge, IA 50501	053501
Fort Dodge Animal Health, Division of American Home Products Corp., 800 Fifth St. NW., Fort Dodge, IA 50501	000856
Franklin Laboratories, Inc., P.O. Box 717, Fort Dodge, IA 50501	010290
Furst-McNess Co., Freeport, IL 61032	010439
Gland-O-Lac Co., 1818 Leavenworth St., Omaha, NE 68102	043735
Golden Sun Feeds, Inc., 111 South Fifth St., Estherville, IA 51334	021780
Michael Gordon, Inc., P.O. Box 8091, San Francisco, CA 94118	049047
Gossett Nutrition, Inc., 1676 Cascade Dr., Marion, OH 43302	050972
G. C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201	010515
Halocarbon Laboratories, Division of Halocarbon Products Corp., 887 Kinderkamack Rd., P.O. Box 661, River Ridge, NJ 07661	012164
Happy Jack, Inc., Snow Hill, NC 28580	023851
Heinold Feeds, Inc., P.O. Box 377, Kouts, IN 46347	043727
Henwood Feed Additives, Division of Feed Specialties Co., Inc., 211 Western Rd., Box 577, Lewisburg, OH 45338	026186
Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525	063604
Hess & Clark, Inc., Seventh and Orange Sts., Ashland, OH 44805	050749
Dow B. Hickam, Inc., Pharmaceuticals, P.O. Box 35413, Houston, TX 77035	000514
Hoechst Roussel Vet, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809–4010. ..	012799
Hubbard Milling Co., 424 North Front St., Mankato, MN 56001	012190
I.M.S. Inc., 13619 Industrial Rd., Omaha, NE 68137	050639
Illini Feeds, Box T, Oneida, IL 61467	037310
IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544	000115
Inhalon Pharmaceuticals, Inc., P.O. Box 21170, Lehigh Valley, PA 18002	060307
International Nutrition, Inc., 7706 'I' Plaza, Omaha, NE 68127	043733

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(1) ALPHABETICAL LISTING OF SPONSORS— Continued

Firm name and address	Drug label- er code
Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966	057926
Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond Street, Overland Park, KS 66214	021641
J. C. Feed Mills, 1050 Sheffield, P.O. Box 224, Waterloo, IA 50704	039741
Jorgensen Laboratories, Inc., 1450 North Van Buren Ave., Loveland, CO 80538	045087
K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214	038782
Kerber Milling Co., Box 152, 1817 E. Main St., Emmetsburg, IA 50536	029341
Koffolk, Inc., P.O. Box 675935, 14735 Las Quintas, Rancho Santa Fe, CA 92067	063271
Lambert-Kay, A Division of Carter-Wallace, Inc., P.O. Box 1001, Half Acre Rd., Cranbury, NJ 08512-0181	011615
Lemmon Co., Sellersville, PA 18960	000693
Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601	061690
Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967	010797
M & M Livestock Products Co., Eagle Grove, IA 50533	026282
Macleod Pharmaceuticals, Inc., 2600 Canton Ct., Fort Collins, CO 80525	058711
Marsam Pharmaceuticals, Inc., Bldg. 31, 24 Olney Ave., Cherry Hill, NJ 08034	000209
Mattox & Moore, Inc., 1503 East Riverside Drive, Indianapolis, IN 46207	027863
McClellan Laboratories, Inc., 19600 Sixth Ave., Lakeview, CA 92353	043738
Medicis Dermatologics, Inc., 8125 North Hayden Rd., Scottsdale, AZ 85258	099207
Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767-1861	051259
Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830-3077	050604
Micro Chemical, Inc., Amarillo, TX 79105	047126
Mid-Continent Agrimarketing, Inc., 8833 Quivira Rd., Overland Park, KS 66214	059620
Monsanto Co., 800 North Lindbergh Blvd., St. Louis, MO 63167	059945
MoorMan's, Inc., 1000 North 30th St., Quincy, IL 62305-3115	021930
Natchez Animal Supply Co., 201 John R. Junkin Dr., Natchez, MS 39120	049968
Nixon and Co., Kiewitt Plaza, Omaha, NE 68501	043729
Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland	055529
Norco Mills of Norfolk, Inc., P.O. Box 56, Norfolk, NE 68701	027190
Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408	058198
Nutra-Blend Corp., P.O. Box 485, Neosho, MO 64850	050568
NutriBasics Co., North Highway 71, P.O. Box 1014, Willmar, MN 56201	053740
Nylos Trading Co., Inc., P.O. Box 2, Route 202, Pomona, NY 10970	027454
Orion Corp. ORION-FARMOS, P.O. Box 425, SF-20101 Turku, Finland	052483
Orphan Medical, Inc., 13911 Ridgedale Dr., Suite 475, Minnetonka, MN 55305	062161
Osborn Laboratories, Inc., 2d and Oak Sts., Le Sueur, MN 56058	012487
OXIS International, Inc., 6040 N. Cutter Circle, Suite 317, Portland, OR 97217-3935	024991

(1) ALPHABETICAL LISTING OF SPONSORS— Continued

Firm name and address	Drug label- er code
Peavey Co., 730 Second Ave. South, Minneapolis, MN 55402	028459
Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514	055246
Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137	053389
Peptech Animal Health Pty, Ltd., 35-41 Waterloo Rd., North Ryde, New South Wales 2113, Australia	064288
Peter Hand Foundation, 2 East Madison St., Waukegan, IL 60085	043737
Pfizer, Inc., 235 East 42d St., New York, NY 10017	000069
Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001-0199	000009
Phoenix Pharmaceutical, Inc., 4621 Easton Rd., P.O. Box 6457 Farleigh Station, St. Joseph, MO 64506-0457	057319
Phoenix Scientific, Inc. 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457	059130
Planalquimica Industrial Ltda., Rua das Magnolias nr. 2405, Jardim das Bandeiras, CEP 13053-120, Campinas, Sao Paulo, Brazil	060728
Pliva d.d., Ulica grada Vukovara 49, 10000 Zagreb, Croatia	011722
PM Resources, Inc., 13001 St. Charles Rock Rd., Bridgeton, MO 63044	060594
Premier Malt Products, Inc., Milwaukee, WI 53201	032707
Protein Blenders, Inc., Box 631, Highway 218 South, Iowa City, IA 52240	033999
Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166-6812	017800
Quali-Tech Products, Inc., 318 Lake Hazeltine Drive, Chaska, MN 55318	016968
The Rath Packing Co., P.O. Box 330, Waterloo, IA 50704	028260
Rhodia Limited, P.O. Box 46, St. Andrews Rd., Avonmouth, Bristol BS11 9YF, England, UK ..	059258
Rhone Merieux Canada, Inc., 345 Boul. Labbe Blvd., North Victoriaville, QC, G6P 1B1 Canada	047015
A. H. Robins Co., P.O. Box 518, Fort Dodge, IA 50501-0518	000031
Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054-1298	063238
RSR Laboratories, Inc., 501 Fifth St., Bristol, TN 37620	058670
R. P. Scherer North America, P.O. Box 5600, Clearwater, FL 33518	011014
Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083	000061
G. D. Searle & Co., P.O. Box 5110, Chicago, IL 60680	000014
Seeco Inc., Box 1014, North Highway 71, Willmar, MN 56201	011749
Shell Chemical Co., Division of Shell Oil Co., Animal Health, One Shell Plaza, Houston, TX 77001	011461
Sioux Biochemical, Inc., 204 Third St. NW., Sioux Center, IA 51250	063112
South St. Paul Feeds, Inc., 500 Farwell Ave., South St. Paul, MN 55075	001800
Southern Micro-Blenders, Inc., 3801 North Hawthorne St., Chattanooga, TN 37406	049685
Springfield Milling Corp., Vigorena Feeds, Springfield, MN 56087	035955
Square Deal Fortification Co., Kouts, IN 46347 ..	036108

(1) ALPHABETICAL LISTING OF SPONSORS—
Continued

Firm name and address	Drug label- er code
Squire Laboratories, Inc., 100 Mill St., Revere, MA 02151	017153
Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043–4705	000402
Sterling Winthrop, Inc., 9 Great Valley Pkwy., Malvern, PA 19355	000934
Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752	037990
Sweetlix, LLC, 175 South Main St., suite 150, Salt Lake City, UT 84111	036904
Syntex Animal Health, Division of Syntex Agribusiness, Inc., 3401 Hillview Ave., Palo Alto, CA 94304	000033
Teva Pharmaceuticals USA, 650 Cathill Rd., Sellersville, PA 18960	000093
Tevcon Ind., Inc., 8904 J St., Omaha, NE 68127	011757
Texas Vitamin Co., P.O. Box 18417, 10695 Aledo St., Dallas, TX 57218	000842
Triple “F”, Inc., 10104 Douglas Ave., Des Moines, IA 50322	011490
United Vaccines, A Harlan Sprague Dawley, Inc., Co., P.O. Box 4220, Madison, WI 53711	058639
V.P.O., Inc., 4444 S. 76th St., Omaha, NE 68127	043743
Vet-A-Mix, Inc., P.O. Box A, Shenandoah, IA 51601	011789
Vetern, S.p.A., Viale E. Bezzi 24, 20146 Milano, Italy	055882
Veterinary Laboratories, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215	000857
Veterinary Research Associates, Inc., 2817 West Country Rd. 54G, Fort Collins, CO 80524	064408
Veterinary Service, Inc., 416 North Jefferson St., P.O. Box 2467, Modesto, CA 95354	033008
Veterinary Specialties Inc., 387 North Valley Ct., Barrington, IL 60010	062925
Vétoquinol N.–A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada, J0K 1H0	059320
Walco International, Inc., 15 West Putnam, Porterville, CA 93257	049185
Waterloo Mills Co., 2050 Mitchell Ave., Waterloo, IA 50704	017139
Wayne Feed Division, Continental Grain Co., P.O. Box 459, Libertyville, IL 60048	034936
Weibel Feeds, Inc., R.R. 3, Pittsfield, IL 62363 ...	035098
Wellmark International, 1100 East Woodfield Rd., suite 500, Schaumburg, IL 60173	011536
Wendt Laboratories, Inc., 100 Nancy Dr., Belle Plaine, MN 56011	015579
West Agro, Inc., 11100 N. Congress Ave., Kansas City, MO 64153	033392
Westchester Veterinary Products, Inc., 180 Mamaroneck Ave., White Plains, NY 10601	043732
Western Chemical, Inc., 1269 Lattimore Rd., Ferndale, WA 98248	050378
Wildlife Laboratories, Inc., 1401 Duff Dr., Suite 600, Fort Collins, CO 80524	053923
Wyeth Laboratories, Division American Home Products Corp., P.O. Box 8299, Philadelphia, PA 19101	000008
Yoder Feed, Division of Yoder, Inc., Kalona, IA 52247	035369
Young's Inc., Roaring Spring, PA 16673	035393
Zema Corp., P.O. Box 12803, Research Triangle Park, Durham, NC 27709	050906

(2) NUMERICAL LISTING OF SPONSORS

Drug labeler code	Firm name and address
000008	Wyeth Laboratories, Division American Home Products Corp., P.O. Box 8299, Philadelphia, PA 19101.
000009	Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199.
000010	Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002.
000014	G. D. Searle & Co., P.O. Box 5110, Chicago, IL 60680.
000031	A. H. Robins Co., P.O. Box 518, Fort Dodge, IA 50501–0518.
000033	Syntex Animal Health Division of Syntex Agribusiness, Inc., 3401 Hillview Ave., Palo Alto, CA 94304.
000056	DuPont Merck Pharmaceutical Co., DuPont Merck Plaza, MR2117, Wilmington, DE 19805.
000061	Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083.
000069	Pfizer, Inc., 235 East 42d St., New York, NY 10017.
000074	Abbott Laboratories, North Chicago, IL 60064.
000093	Teva Pharmaceuticals USA, 650 Cathill Rd., Sellersville, PA 18960.
000115	IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
000185	Eon Labs Manufacturing, Inc., 227-15 North Conduit Ave., Laurelton, NY 11413.
000209	Marsam Pharmaceuticals, Inc., Bldg. 31, 24 Olney Ave., Cherry Hill, NJ 08034.
000332	Biocraft Laboratories, Inc., 92 Route 46, Elmwood Park, NJ 07407.
000402	Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043–4705.
000514	Dow B. Hickam, Inc., Pharmaceuticals, P.O. Box 35413, Houston, TX 77035.
000693	Lemmon Co., Sellersville, PA 18960.
000842	Texas Vitamin Co., P.O. Box 18417, 10695 Aledo St., Dallas, TX 57218.
000856	Fort Dodge Animal Health, Division of American Home Products Corp., 800 Fifth St. NW., Fort Dodge, IA 50501.
000857	Veterinary Laboratories, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215.
000859	Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201.
000864	Anthony Products Co., 5600 Peck Rd., Arcadia, CA 91006.
000934	Sterling Winthrop, Inc., 9 Great Valley Pkwy., Malvern, PA 19335.
000986	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.
001800	South St. Paul Feeds, Inc., 500 Farwell Ave., South St. Paul, MN 55075.
010019	Baxter Pharmaceutical Products, Inc., 110 Allen Rd., Liberty Corner, NJ 07938–0804.
010042	American Cyanamid, Division of American Home Products, P.O. Box 1339, Fort Dodge, IA 50501.
010290	Franklin Laboratories, Inc., P.O. Box 717, Fort Dodge, IA 50501.
010290	Franklin Laboratories, P.O. Box 669, Amarillo, TX 79105.
010439	Furst-McNess Co., Freeport, IL 61032.
010515	G. C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201.

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(2) NUMERICAL LISTING OF SPONSORS— Continued

Drug labeler code	Firm name and address
010797	Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967.
011014	R. P. Scherer North America, P.O. Box 5600, Clearwater, FL 33518.
011461	Shell Chemical Co., Division of Shell Oil Co., Animal Health, One Shell Plaza, Houston, TX 77001.
011485	Albion Laboratories, Inc., 101 North Main, Clearfield, UT 84015.
011490	Triple "F", Inc., 10104 Douglas Ave., Des Moines, IA 50322
011509	Combe, Inc., 1101 Westchester Ave., White Plains, NY 10604.
011526	Aventis Animal Nutrition, Inc., 3480 Preston Ridge Rd., suite 650, Alpharetta, GA 30005-8891
011536	Wellmark International, 1100 East Woodfield Rd., suite 500, Schaumburg, IL 60173
011615	Lambert-Kay, A Division of Carter-Wallace, Inc., P.O. Box 1001, Half Acre Rd., Cranbury, NJ 08512-0181.
011722	Pliva d.d., Ulica grada Vukovara 49, 10000 Zagreb, Croatia
011749	Seeco Inc., Box 1014, North Highway 71, Willmar, MN 56201.
011789	Vet-A-Mix, Inc., P.O. Box A, Shenandoah, IA 51601.
012164	Halocarbon Laboratories, Division of Halocarbon Products Corp., 887 Kinderkamack Rd., P.O. Box 661, River Ridge, NJ 07661.
012190	Hubbard Milling Co., 424 North Front St., Mankato, MN 56001.
012487	Osborn Laboratories, Inc., 2d and Oak Sts., Le Sueur, MN 56058.
012799	Hoehchst Roussel Vet, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809-4010.
015565	Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234.
015579	Wendt Laboratories, Inc., 100 Nancy Dr., Belle Plaine, MN 56011.
016968	Quali-Tech Products, Inc., 318 Lake Hazeltine Dr., Chaska, MN 55318.
017030	Evsco Pharmaceuticals, An Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
017135	Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013-3928.
017139	Waterloo Mills Co., 2050 Mitchell Ave., Waterloo, IA 50704.
017153	Squire Laboratories, Inc., 100 Mill St., Revere, MA 02151.
017287	Chemdex, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215.
017473	Custom Feed Services Corp., 2100 N. 13th St., Norfolk, NE 68701.
017519	ADM Animal Health & Nutrition Division, 1000 North 30th St., Box 1C, Quincy, IL 62305-3115
017762	Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112.
017790	Akey, Inc., P.O. Box 607, Lewisburg, OH 45338.
017800	Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166-6812.
021091	ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105.

(2) NUMERICAL LISTING OF SPONSORS— Continued

Drug labeler code	Firm name and address
021641	Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond Street, Overland Park, KS 66214.
021676	Farmland Industries, Inc., Kansas City, MO 64116.
021780	Golden Sun Feeds, Inc., 111 South Fifth St., Estherville, IA 51334.
021930	MoorMan's, Inc., 1000 North 30th St., Quincy, IL 62305-3115.
023851	Happy Jack, Inc., Snow Hill, NC 28580.
024174	Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464.
024991	OXIS International, Inc., 6040 N. Cutter Circle, Suite 317 Portland, OR 97217-3935.
025001	Diamond Shamrock Corp., Nutrition & Animal Health Div., 1100 Superior Ave., Cleveland, OH 44114.
025463	Altana Inc., 60 Baylis Rd., Melville, NY 11747.
026186	Henwood Feed Additives, Division of Feed Specialties Co., Inc., 211 Western Rd., Box 577, Lewisburg, OH 45338.
026282	M & M Livestock Products Co., Eagle Grove, IA 50533.
027190	Norco Mills of Norfolk, Inc., P.O. Box 56, Norfolk, NE 68701.
027454	Nylos Trading Co., Inc., P.O. Box 2, Route 202, Pomona, NY 10970.
027863	Mattox & Moore, Inc., 1503 East Riverside Dr., Indianapolis, IN 46207.
028260	The Rath Packing Co., P.O. Box 330, Waterloo, IA 50704.
028459	Peavey Co., 730 Second Ave. South, Minneapolis, MN 55402.
029341	Kerber Milling Co., Box 152, 1817 E. Main St., Emmetsburg, IA 50536.
030841	Feed Service Co., Inc., 303 Lundin Blvd., P.O. Box 698, Mankato, MN 56001.
032707	Premier Malt Products, Inc., Milwaukee, WI 53201.
032761	BioScience Division of Milk Specialties Co., Illinois and Water Sts., P.O. Box 278, Dundee, IL 60118.
033008	Veterinary Service, Inc., 416 North Jefferson St., P.O. Box 2467, Modesto, CA 95354.
033392	West Agro, Inc., 11100 N. Congress Ave., Kansas City, MO 64153.
033999	Protein Blenders, Inc., Box 631, Highway 218 South, Iowa City, IA 52240.
034936	Wayne Feed Division, Continental Grain Co., P.O. Box 459, Libertyville, IL 60048.
035098	Webel Feeds, Inc., R.R. 3, Pittsfield, IL 62363.
035369	Yoder Feed, Division of Yoder, Inc., Kalona, IA 52247.
035393	Young's, Inc., Roaring Spring, PA 16673.
035955	Springfield Milling Corp., Vigorena Feeds, Springfield, MN 56087.
036108	Square Deal Fortification Co., Kouts, IN 46347.
036904	Sweetlix, LLC, 175 South Main St., suite 150, Salt Lake City, UT 84111.
037310	Illini Feeds, Box T, Oneida, IL 61467.
037990	Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752.
038782	K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214.
039741	J. C. Feed Mills, 1050 Sheffield, P.O. Box 224, Waterloo, IA 50704.

(2) NUMERICAL LISTING OF SPONSORS—
Continued

Drug labeler code	Firm name and address
043727	Heinold Feeds, Inc., P.O. Box 377, Kouts, IN 46347.
043728	Balfour Guthrie & Co., Ltd., 315 North H St., Fresno, CA 93701.
043729	Nixon and Co., Kiewitt Plaza, Omaha, NE 68501.
043732	Westchester Veterinary Products, Inc., 180 Mamaroneck Ave., White Plains, NY 10601.
043733	International Nutrition, Inc., 7706 'I' Plaza, Omaha, NE 68127.
043735	Gland-O-Lac Co., 1818 Leavenworth St., Omaha, NE 68102.
043737	Peter Hand Foundation, 2 East Madison St., Waukegan, IL 60085.
043738	McClellan Laboratories, Inc., 19600 Sixth Ave., Lakeview, CA 92353.
043743	V.P.O., Inc., 4444 South 76th St., Omaha, NE 68127.
043744	Farmers Feed & Supply Co., Ninth St. at Northwestern Tracks, Tipton, IA 52772.
043781	Cyanamid Agricultural de Puerto Rico, Inc., P.O. Box 243, Manati, PR 00701.
045087	Jorgensen Laboratories, Inc., 1450 North Van Buren Ave., Loveland, CO 80538.
046573	Alpharma Inc., One Executive Drive, P.O. Box 1399, Fort Lee, NJ 07024.
046987	Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501.
047015	Rhone Merieux Canada, Inc., 345 Boul. Labbe Blvd., North Victoriaville, QC, G6P 1B1 Canada.
047019	Carnation Co., 5045 Wilshire Blvd., Los Angeles, CA 90036.
047126	Micro Chemical, Inc., Amarillo, TX 79105.
049047	Michael Gordon, Inc., P.O. Box 1091, San Francisco, CA 94118.
049185	Walco International, Inc., 15 West Putnam, Porterville, CA 93257.
049685	Southern Micro-Blenders, Inc., 3801 North Hawthorne St., Chattanooga, TN 37406.
049968	Natchez Animal Supply Co., 201 John R. Junkin Dr., Natchez, MS 39120.
050378	Western Chemical, Inc., 1269 Lattimore Rd., Ferndale, WA 98248.
050568	Nutra-Blend Corp., P.O. Box 485, Neosho, MO 64850.
050604	Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077.
050639	I.M.S. Inc., 13619 Industrial Rd., Omaha, NE 68137.
050749	Hess & Clark, Inc., Seventh and Orange Sts., Ashland, OH 44805.
050906	Zema Corp., P.O. Box 12803, Research Triangle Park, Durham, NC 27709.
050972	Gossett Nutrition, Inc., 1676 Cascade Dr., Marion, OH 43302.
051212	Argent Laboratories, 8702 152d Ave. NE., Redmond, WA 98052.
051259	Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861.
051267	Cooperative Research Farms, Box 69, Charlotteville, NY 12036.
051359	Bioproducts, Inc., 320 Springside Dr., Suite 300, Fairlawn, OH 44141.
052483	Orion Corp. ORION-FARMOS, P.O. Box 425, SF–20101 Turku, Finland.
053389	Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137.

(2) NUMERICAL LISTING OF SPONSORS—
Continued

Drug labeler code	Firm name and address
053501	Fort Dodge Animal Health, A Division of American Cyanamid Co., P.O. Box 1339, Fort Dodge, IA 50501.
053740	NutriBasics Co., North Highway 71, P.O. Box 1014, Willmar, MN 56201.
053923	Wildlife Laboratories, Inc., 1401 Duff Dr., Suite 600, Fort Collins, CO 80524.
055246	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.
055462	Contemporary Products, Inc., 3788 Elm Springs Rd., Springdale, AR 72764–6067.
055529	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.
055882	Vetem, S.p.A., Viale E. Bezzi 24, 20146 Milano, Italy.
057319	Phoenix Pharmaceutical, Inc., 4621 Easton Rd., P.O. Box 6457 Farleigh Station, St. Joseph, MO 64506–0457.
057561	Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503.
057926	Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966.
058034	John J. Ferrante, 11 Fairway Lane, Trumbull, CT 06611.
058198	Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408.
058639	United Vaccines, A Harlan Sprague Dawley, Inc., Co., P.O. Box 4220, Madison, WI 53711.
058670	RSR Laboratories, Inc., 501 Fifth St., Bristol, TN 37620.
058711	Macleod Pharmaceuticals, Inc., 2600 Canton Ct., Fort Collins, CO 80525.
058829	First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123.
059079	Delmarva Laboratories, Inc., 2200 Wadebridge Rd., P.O. Box 525, Midlothian, VA 23113.
059130	Phoenix Scientific, Inc. 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457.
059258	Rhodia Limited, P.O. Box 46, St. Andrews Rd., Avonmouth, Bristol BS11 9YF, England, UK.
059320	Vétoquinol N.–A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada, J0K 1H0.
059945	Monsanto Co., 800 North Lindbergh Blvd., St. Louis, MO 63167.
059521	Ausa International, Inc., Rt. 8, P.O. Box 324–12, Tyler, TX 75703.
059620	Mid-Continent Agrimarketing, Inc., 8833 Quivira Rd., Overland Park, KS 66214.Bld., St. Louis, MO 63167.
060307	Inhalon Pharmaceuticals, Inc., P.O. Box 21170, Lehigh Valley, PA 18002.
060594	PM Resources, Inc., 13001 St. Charles Rock Rd., Bridgeton, MO 63044.
060728	Planalquímica Industrial Ltda., Rua das Magnolias nr. Jardim das Bandeiras, CEP 13053–120, Campinas, Sao Alto, Brazil.
060865	Anika Therapeutics Inc., 236 West Cummings Park, Woburn, MA 01801.
060951	Endo Pharmaceuticals, Inc., 223 Wilmington West Chester Pike, Chadds Ford, PA 19317.

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(2) NUMERICAL LISTING OF SPONSORS— Continued

Drug labeler code	Firm name and address
061133	Bimeda, Inc., 288 County Rd. 28, LeSueur, MN 56058-9322
061623	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.
061651	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland.
061690	Lloyd, Inc., 604 W. Thomas Ave., Shendoah, IA 51601.
062161	Orphan Medical, Inc., 13911 Ridgedale Dr., Suite 475, Minnetonka, MN 55305.
062240	Equi Aid Products, Inc., 1517 West Knudsen Dr., Phoenix, AZ 85027.
062408	Alstoe, Ltd., Animal Health, Granary Chambers, 37-39 Burton St., Melton Mowbray, Leicestershire LE13 1AF, England.
062925	Veterinary Specialties Inc., 387 North Valley Ct., Barrington, IL 60010.
063075	Biopure Corp., 11 Hurley St., Cambridge, MA 02141.
063112	Sioux Biochemical, Inc., 204 Third St. NW., Sioux Center, IA 51250.
063238	Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054-1298.
063271	Koffolk, Inc., P.O. Box 675935, 14735 Las Quintas, Rancho Santa Fe, CA 92067.
063323	American Pharmaceuticals Partners, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160.
063604	Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525.
063765	Akzo Nobel Surface Chemistry AB, Box 851, S-44485 Stenungsund, Sweden.
064146	Alaco, Inc., 1500 North Wilmot Rd., suite 290-C, Tucson, AZ 85712.
064288	Peptech Animal Health Pty, Ltd., 35-41 Waterloo Rd., North Ryde, New South Wales 2113, Australia.
064408	Veterinary Research Associates, Inc., 2817 West Country Rd. 54G, Fort Collins, CO 80524.
065274	Blue Ridge Pharmaceuticals, Inc., 4249-105 Piedmont Pkwy., Greensboro, NC 27410.
099207	Medicis Dermatologics, Inc., 8125 North Hayden Rd., Scottsdale, AZ 85258

[40 FR 13807, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §510.600, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 360b, 371.

§511.1 New animal drugs for investigational use exempt from section 512(a) of the act.

(a) *New animal drugs for tests in vitro and in laboratory research animals.* (1) A

shipment or other delivery of a new animal drug or animal feed bearing or containing a new animal drug intended solely for tests in vitro or in animals used only for laboratory research purposes shall be exempt from section 512 (a) and (m) of the act if it is labeled as follows:

Caution. Contains a new animal drug for investigational use only in laboratory research animals or for tests in vitro. Not for use in humans.

(2) The person distributing or causing the distribution of new animal drugs for tests in vitro or in animals used only for laboratory research purposes under this exemption shall use due diligence to assure that the consignee is regularly engaged in conducting such tests and that the shipment of the new animal drug will actually be used for tests in vitro or in animals used only for laboratory research.

(3) The person who introduced such shipment or who delivered the new animal drug for introduction into interstate commerce shall maintain adequate records showing the name and post office address of the expert or expert organization to whom the new animal drug is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department at reasonable times, he shall make such records available for inspection and copying.

(4) The exemption allowed in this paragraph shall not apply to any new animal drug intended for in vitro use in the regular course of diagnosing or treating disease, including antibacterial sensitivity discs impregnated with any new animal drug or drugs, which discs are intended for use in determining susceptibility of microorganisms to the new animal drug or drugs.

(b) *New animal drugs for clinical investigation in animals.* A shipment or other delivery of a new animal drug or an animal feed containing a new animal drug intended for clinical investigational use in animals shall be exempt from section 512(a) and (m) of the act if all the following conditions are met:

(1) The label shall bear the statements: